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Dated: March 26, 2010
Electronic Signature for Jill Gorny Sloper: /Jill Gorny Sloper/

Docket No.: HLZ-001USRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Mats Paulsson *et al.*

Application No.: 10/019067

Confirmation No.: 7795

Filed: June 28, 2002

Art Unit: 1641

For: DIAGNOSIS OF GLUTEN SENSITIVE
ENTEROPATHY AND OTHER
AUTOIMMUNOPATHIES

Examiner: COUNTS, Gary W.

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b)” for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **1164 days**, with an additional term to be added based on the number of days following payment of the issue fee to the date of issuance of a patent for the above-referenced application.

2. The patent term adjustment on the Determination of Patent Term Adjustment Under 35 U.S.C. §154(b) (“Determination”) that was attached to the Notice of Allowance is 29 days (a copy of the Determination is submitted herewith as Exhibit A). A copy of the PTO’s Patent Term Adjustment calculation (“PTA Sheet”) available on Private Pair is also submitted herewith as Exhibit B. Applicants respectfully submit that the determination of 29 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance with 37 CFR §1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by August 28, 2003). As shown in Exhibit A, the Office failed to mail an action under 35 U.S.C. §132 (a Restriction Requirement) until April 28, 2005. As such, Patentees are entitled to a period of patent term adjustment beginning August 29, 2002 and ending on April 28, 2005, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is **609 days**. This is consistent with the PTA Sheet (Exhibit A) from the Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

It is anticipated that the Office will not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a) (*i.e.*, by December 28, 2004). As indicated in the Notice of Allowance, a patent is projected to issue on July 6, 2010. As such, there is an anticipated delay of **2016 days**.

However, since the exclusionary period for continued examination set forth in 37 CFR §1.702(b)(1) applies to the instant patent, the number of days in the period beginning on the date on which Patentees first filed a Request for Continued Examination (August 22, 2008) and ending on the future issue date of a corresponding patent (July 6, 2010), *i.e.*, 684 days, is excluded from the period of Three Years Delay. Therefore, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of Three Years Delay based on the period of time beginning on the day after the date that is three years after the date on which the above-referenced patent was filed under 35 U.S.C. § 111(a) (*i.e.*, December 28, 2004), and ending on the date Patentees first filed a Request for Continued Examination (*i.e.*, August 22, 2008). This period of delay is **1332 days**.

Applicants respectfully note that a first Notice of Appeal was filed on January 23, 2008. Pursuant to 37 CFR 1.702(b)(4) the requirement that the Office must issue a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a) does not include the period of appellate review by the BPAI or a Federal Court. However, as the Notice of Appeal that was filed on January 23, 2008 was effectively withdrawn by the subsequent Request for Reconsideration that was filed on August 22, 2008, the Exclusion for Appellate Review does not affect the present calculation.

Applicants also note that a second Notice of Appeal was filed in December 8, 2009. However, as the Notice of Appeal that was filed on December 8, 2009 was effectively withdrawn by the subsequent Notice of Allowance on December 29, 2009, the Exclusion for Appellate Review does not affect the present calculation.

(iii) **Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)**

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (609 days) and the minimum period of Three Years Delay (1332 days), or **1941 days**, to the extent these periods of delay are not overlapping. In this regard, Applicants note that the period of the 14 Month PTO Delay and the Three Year PTO Delay overlap between December 28, 2004 and April 28, 2005, *i.e.*, by **121 days**. Accordingly, the sum of the total examination delays (1941) is reduced by the period of overlap (121 days), resulting in a total examination delay of **1820 days**.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704, the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the PTO’s Patent Term Adjustment calculation (Exhibit B), the Office has calculated a period of Applicant Delay of 580 days. Applicants respectfully submit that the correct period of Applicant Delay is **656 days** and seek correction based on the following remarks.

(i) Applicant Delay for Responding to Notice to File Missing Parts

Applicants respectfully submit that a period of Applicant Delay of **27 days** accrued for the delayed submission of Response to Notification of Missing Requirements on June 28, 2002. This period is not shown on Exhibit B, the PTA Sheet from the Office. Pursuant to 37 CFR §1.704(b), this 27 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(ii) Applicant Delay for Responding to Restriction Requirement Dated April 28, 2005

Applicants respectfully submit that an additional period of Applicant Delay of **92 days** accrued for the delayed submission of a Response to the Restriction Requirement on October 28, 2005. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 92 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iii) Applicant Delay for Filing an Information Disclosure Statement

Applicants respectfully submit that an additional period of Applicant Delay of **38 days** accrued for the delayed submission of an Information Disclosure Statement (IDS) on December 5, 2005. This IDS was filed without a statement under 37 CFR §1.704(d), 38 days after the filing of a Response to the Restriction Requirement on October 28, 2005. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 92 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Applicant Delay for Responding to Restriction Requirement and Notice to Comply with Sequence Requirements Dated February 6, 2006

Applicants respectfully submit that an additional period of Applicant Delay of **93 days** accrued for the delayed submission of a Response to the Restriction Requirement and Notice to Comply with Sequence Requirements on August 7, 2006. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 93 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(v) Reply Having Omission

Applicants respectfully submit that an additional period of Applicant Delay of **49 days** accrued for the submission of a Non-Responsive Amendment on August 7, 2006. This Non-Responsive Amendment is considered a “reply having an omission.” Therefore, pursuant to 37 CFR §1.704(c)(7), the period of adjustment shall be reduced by the number of days beginning on the day after the date the reply having an omission was filed (*i.e.*, August 8, 2006) and ending on the date that the reply correcting the omission was filed (*i.e.*, September 25, 2006), or 49 days.

This period is not shown on Exhibit B, the PTA Sheet from the Office. Pursuant to 37 CFR §1.704(c)(7), this **49 day** period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(vi) Applicant Delay for Responding to Non-Final Office Action Dated November 6, 2006

Applicants respectfully submit that an additional period of Applicant Delay of **87 days** accrued for the delayed submission of an Amendment and Response to the Non-Final Office Action on May 4, 2007. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 87 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(vii) Applicant Delay for Responding to Final Office Action Dated July 24, 2007

Applicants respectfully submit that an additional period of Applicant Delay of **91 days** accrued for the delayed filing of a Notice of Appeal on January 23, 2008. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 91 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(viii) Applicant Delay for Responding to Non-Final Office Action Dated September 17, 2008

Applicants respectfully submit that an additional period of Applicant Delay of **90 days** accrued for the delayed submission of an Amendment and Response to the Non-Final Office Action on March 17, 2009. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 90 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(ix) Applicant Delay for Responding to Final Office Action Dated June 10, 2009

Applicants respectfully submit that an additional period of Applicant Delay of **89 days** accrued for the delayed filing of a Notice of Appeal on December 8, 2009. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 89 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(x) Calculation of the Total Period of Applicant Delay

In view of the above, Applicants have calculated a total period of Applicant Delay of **656 days** which is the sum of the following Applicant Delays: (i) the 27 day period; (ii) the 92 day period ; (iii) the 38 day period; (iv) the 93 day period ; (v) the 49 day period; (vi) the 87 day period; (vii) the 91 day period, (viii) the 90 day period, and (ix) the 89 day period. Accordingly, Applicants respectfully submit that the correct period of Applicant Delay is **656 days**, not 580 days, and request appropriate correction by the Office.

C. **Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)**

As set forth in 37 CFR §1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is **at least 1164 days**, which is the difference between the total period of examination delay (1820 days) and the period of Applicant Delay (656 days). Applicants further submit that the term of **1164 days** should be extended by an additional term equal to the number of days following payment of the issue fee to the date of issuance of a patent for the above-referenced application in accordance with 37 CFR §1.703(b). **As such, the correct patent term adjustment upon issuance of a patent is expected to be the sum of 1164 days (as calculated herein) and the number of days from payment of the issue fee to issuance of a patent.**

4. In accordance with 37 CFR§1.705(b)(2)(iii), Applicants submit that the pending patent corresponding to this application is not subject to a terminal disclaimer.

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of **1164 days**, with an additional term to be added based on the number of days following payment of the issue fee to the date of issuance of a patent for the above-referenced application.

Dated: March 26, 2010

Respectfully submitted,

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